

2014-02

# The influence of soft contact lens wear and two weeks cessation of lens wear on corneal curvature.

Lloyd McKernan, A

<http://hdl.handle.net/10026.1/13481>

---

10.1016/j.clae.2013.07.014

Cont Lens Anterior Eye

---

*All content in PEARL is protected by copyright law. Author manuscripts are made available in accordance with publisher policies. Please cite only the published version using the details provided on the item record or document. In the absence of an open licence (e.g. Creative Commons), permissions for further reuse of content should be sought from the publisher or author.*



2014-2

# The Influence of Soft Contact Lens Wear and Two Weeks Cessation of Lens Wear on Corneal Curvature

Aoife Lloyd McKernan

*Dublin Institute of Technology, aoifemarie.lloyd@dit.ie*

Veronica O'Dwyer

*Dublin Institute of Technology*

Luisa Simo Mannion

*Plymouth University*

Follow this and additional works at: <http://arrow.dit.ie/otpomart>



Part of the [Ophthalmology Commons](#)

## Recommended Citation

Lloyd McKernan, A, O'Dwyer, V, Simo Mannion, L., The influence of soft contact lens wear and two weeks lens cessation on corneal curvature. *Contact Lens Anterior Eye*. Feb 2014, 37 (1) : 31-37.

This Article is brought to you for free and open access by the Department of Optometry at ARROW@DIT. It has been accepted for inclusion in Articles by an authorized administrator of ARROW@DIT. For more information, please contact [yvonne.desmond@dit.ie](mailto:yvonne.desmond@dit.ie), [arrow.admin@dit.ie](mailto:arrow.admin@dit.ie), [brian.widdis@dit.ie](mailto:brian.widdis@dit.ie).



This work is licensed under a [Creative Commons Attribution-Noncommercial-Share Alike 3.0 License](#)



**Title**

The influence of soft contact lens wear and two weeks cessation of lens wear on corneal curvature.

**Author(s)**

Aoife Lloyd McKernan<sup>1</sup>

Veronica O'Dwyer<sup>1</sup>

Luisa Simo Mannion<sup>2</sup>

<sup>1</sup>Dublin Institute of Technology, <sup>2</sup> Plymouth University.

## **Abstract and key words**

**Introduction:** Accurate corneal measurements are crucial in corneal refractive surgery (CRS) to ensure successful outcomes. Soft contact lens (SCL) wear may result in changes to corneal curvature and structure. United States Food and Drug Administration (FDA) pre-operative guidelines recommend that prior to CRS, SCL wearers cease SCL wear for “at least two weeks before examination and treatment” [1]. Corneal curvature changes induced by SCL wear may take longer than two weeks to resolve.

**Purpose:** To examine the effect of SCL wear on corneal curvature before and following two weeks cessation of lens wear. To explore the possible impact of different SCL materials and years of SCL wear.

**Methods:** Retrospective data analysis, between a group of SCL wearers (SCL: n=45); and a non-contact lens control group (NCL: n=45). Corneal curvature parameters were measured using the Pentacam (Oculus, Germany), before and following two weeks cessation of SCL wear.

**Results:** No significant differences in keratometry or Sagittal radius of curvature between SCL and NCL groups prior to or following SCL cessation. Tangential radius of curvature showed significant inferior steepening for the SCL group prior to SCL cessation (SCL vs. NCL;  $7.77 \pm 0.30$  mm vs.  $7.90 \pm 0.30$ mm;  $p= 0.04$ ). Following two weeks cessation of SCL wear this appeared to have resolved.

**Conclusions:** Two weeks cessation of SCL wear appears sufficient for resolution of corneal curvature changes with modern SCL materials and years of SCL wear. However, further

studies with longer lens deprivation periods are required to ensure stability for all SCL wearing patients.

**Key words**

Cornea

Soft contact lens

Topography

Pentacam

## Introduction

A significant proportion of candidates for CRS wear SCLs. SCL wear can result in changes to the corneal structure and metabolism. The time required for resolution of these changes can vary according to contact lens (CL) material, modality and length of previous CL wear [2-4]. The FDA guidelines recommend that SCLs are left out for at least two weeks prior to initial consultation, however no specific guidelines are given in relation to SCL type, modality or previous years of SCL wear [1]. To the author's knowledge, no published study has examined retrospective findings from a SCL group of various lens materials and years of SCL wear and evaluated corneal stability following two weeks lens cessation, in relation to a NCL group.

Accurate corneal curvature measurements are vital prior to CRS to determine the treatment type and generate treatment plans. Corneal topography is the most sensitive pre-operative screening tool used for diseases such as forme fruste keratoconus and for contact lens-induced corneal warpage [5].

SCL wear has been found to result in significant changes to mean keratometry, corneal astigmatism and corneal eccentricity [6]. Following initial flattening of keratometry values [7], anterior corneal topography and keratometry values steepen in all corneal meridians with hydrogel SCL wear [7-10]. Increased corneal irregularity and corneal warpage or pseudo-keratoconic topography have been reported with daily wear of low oxygen transmissibility (DK/t) hydrogel SCLs [6, 11, 12]. High DK/t silicone hydrogel (SiH) SCLs reduce complications associated with hypoxia [13]. However, stiff modulus SiH lenses worn for longer wearing times can result in flattening of keratometry values [6, 14-18].

The amount of time required to eliminate the alterations to corneal curvature is dependent on CL material, modality and years of previous SCL wear [3, 4, 19-21]. Corneal curvature

measurements show stability following two weeks cessation of SCL wear for most patients [2]. However, in some cases, resolution of stability of corneal measurements can take weeks or months following cessation of SCL wear [3, 16, 20, 21]. Resolution of alterations to curvature induced by SiH wear can take longer than three months in some cases [10, 16].

The purpose of this study is to explore whether a standard SCL cessation time of two weeks, is sufficient to allow the cornea to recover from SCL wear and to assess the possible impact of a variety of modern SCL materials and years of SCL wear on corneal curvature prior to and following two weeks lens wear cessation.

## **Methods**

This was a retrospective, non-masked analysis on data from a group of patients (n=90), who attended a CRS clinic. Informed consent was obtained from patients to allow their data to be used anonymously for the purpose of research. This study was approved by the Ethics Committee of Dublin Institute of Technology, and it adhered to the tenets of the Declaration of Helsinki [22].

Patients attending the clinic were determined to be suitable for CRS if they achieved the suitability guidelines published by the United States FDA[1] for refractive Laser procedures. Dominant eyes only were analysed in order to account for the correlation, which exists between right and left eyes of a subject, and to avoid overstatement of the validity of statistical analysis [23-25]. Myopic prescriptions incorporating astigmatism of less than -1.50DC were included for analysis.

The full-time SCL group was comprised of patients wearing SCLs at least five days a week, for at least one year, before attending the clinic. This group was further divided according to

lens material (hydrogel and SiH) and previous years of SCL wear (<5, 5-10, >10 years). The SCL group wore disposable SCLs (replaced on a daily/weekly/two-weekly or monthly basis). These groupings were based on the information relating to the most recent year of SCL wear.

The NCL group was comprised of patients with no history of CL wear. Previous RGP CL wearers and patients with a history of previous CRS were excluded from the study.

Patients were asked to cease SCL wear the evening before they attended the clinic for their first assessment. All patients in the SCL group were asked to cease SCL wear for a period of 2 weeks prior to attending the clinic for a second assessment, regardless of previous SCL material or modality of wear.

Corneal curvature analysis was undertaken using the Pentacam tomographer (Oculus, Germany). Simulated keratometry (SimK) values and Sagittal and Tangential radius of curvature values (centrally and at a 4.5mm diameter superior and inferior to centre) were analysed. Corneal surface measurement data (curvature data, height data, Fourier analysis and Zernike analysis) are used to calculate topographical indices with the Pentacam tomographer (Oculus, Germany). These indices help in the detection of abnormalities on the corneal surface and are useful in screening patients prior to CRS. These indices were analysed for SCL and NCL groups in this study.

Corneal curvature was assessed prior to cessation of SCL wear and following two weeks lens cessation. Measurements were also repeated for the NCL group. The differences between repeated measurements from the SCL group and NCL group were examined, in order to assess whether there was more variation in corneal curvature in the SCL wearing group.



Statistical analysis was carried out using the software package SPSS 20 (SPSS Inc., Chicago, Illinois, USA). The statistical programme G\*Power 3.1.2 was used to ascertain which sample size was sufficient to ensure statistical power, n=82 was found to be sufficient[26].

Normality for continuous data were assessed using Shapiro-Wilks method (normal distribution when  $p > 0.05$ )[27]. Data that were found to have normal distribution were analysed using a two-way ANOVA. Data that did not show a normal distribution were assessed using the Kruskal-Wallis test. An alpha value of  $p < 0.05$  was considered significant.

## Results

All patients were of Caucasian ethnicity, see table 1 for population demographics. The SCL group had a higher mean spherical equivalent refractive error than the NCL group (SCL:  $-3.73 \pm 1.65$ DS, NCL:  $-2.56 \pm 1.48$ DS,  $p=0.01$ ). There was no significant difference between the astigmatic refractive error between the groups (SCL:  $-0.58 \pm 0.25$ DC, NCL:  $-0.63 \pm 0.34$ DC,  $p=0.94$ ).

## Patient demographics

	<b>Gender % Male : Female</b>	<b>Age Mean <math>\pm</math> SD years</b>	<b>LogMAR VA Mean <math>\pm</math> SD</b>
<b>SCL (n=45)</b>	51:49	32 $\pm$ 7.5	-0.13 $\pm$ 0.01
<b>NCL (n=45)</b>	64:36	37 $\pm$ 10	-0.11 $\pm$ 0.01

*Table 1: Patient demographics showing gender, age and visual acuity (VA) data for soft contact lens (SCL) and non-contact lens control group (NCL).*

SCLs were worn for a mean of  $9 \pm 4.5$  years (range 1 to 22 years),  $6.5 \pm 1$  days per week (range 5 to 7 days) and  $12 \pm 5$  hours per day (range 4 to 24 hours) prior to consultation.

Thirty-five patients wore hydrogel SCLs (77.7%), six patients wore SiH SCLs (13.3%, 3 generation 1 SiH and 3 generation 2 SiH), and four patients did not know their CL material type (8.8%). Of the SiH group, 50% wore their lenses on an extended wear modality (24 hours per day) and 50% wore their lenses as a daily wear lens (mean 12 hours, range 8-16 hours per day). Two subjects wore toric SCL with a cylinder correction of -0.75 (dual thin zone design) and -1.25 (accelerated stabilisation design).

### Diurnal variation

Corneal curvature values can vary according to the time the measurement was taken [28], this diurnal variation pattern shows greatest changes upon awakening, with flattening of the anterior cornea and steepening of the posterior cornea evident. This pattern tends to settle as the day progresses [28]. Pentacam measurements in this study were taken during normal clinic hours (8.30 to 19.00 hours). The time of Pentacam measurement taken at the first and second visit was analysed statistically using Mann Whitney U testing to explore the differences in mean time of measurements between the groups (SCL vs. NCL). Results (displayed in Table 2) show there was no statistically significant differences between the groups at first or second visit.

### Time of corneal thickness measurements

<b>Time of measurement</b>	<b>SCL group (n=45)</b>	<b>NCL group (n=45)</b>	<b>P value</b>
First visit (hours)	12.66 $\pm$ 2.55	12.44 $\pm$ 2.91	0.455
Second visit (hours)	13.56 $\pm$ 2.70	13.59 $\pm$ 2.90	0.932

*Table 2: Time of Pentacam measurements. Mean  $\pm$  SD and results of Mann Whitney U testing for the time of Pentacam measurements taken at first visit and second visit, ( $p < 0.05$ ).*

In order to investigate the possible effect of diurnal variation on corneal curvature values, the groups (SCL vs. NCL) were divided into morning (where measurements were taken before 14.00 hours) and afternoon (where measurements were taken after 14.00 hours) groups. Two-

way ANOVA test results showed there was no statistically significant difference in corneal curvature measurements taken in the morning or afternoon for either the SCL or NCL groups ( $p>0.05$ ). As there was no significant differences in the time that Pentacam measurements were taken at first or second visits, and because there was no significant influence of the time of measurements on the corneal curvature, it was decided not to divide groups according to when measurements were taken for corneal curvature analysis.

### **Follow up compliance for second visit**

The retrospective nature of our study is a limitation. There was a reduction in the sample size at the second visit ( $n=8$  NCL and  $n=7$  SCL wearers). These patients were not included as they did not have corneal curvature measurements repeated or had poor quality Pentacam scans taken at the second visit. Of the seven SCL wearers who were not included for their second visit, six were hydrogel SCL wearers and one was a generation 2 SiH SCL wearer. The inferior Tangential curvature values of these patients did not vary significantly from the mean value at first visit.

### **Corneal curvature at first visit**

At the first visit, although curvature was steeper in the SCL group, there were no significant differences in SimK or Sagittal radii between the SCL and NCL groups (see table 3). Anterior Tangential radius of curvature showed signs of corneal warpage to be present: the inferior radii were significantly lower in the SCL group (7.77mm), indicating steepening, compared to the NCL group (7.90mm),  $F(1, 88) = 4.25$ ,  $p=0.04$ . Superior Tangential radii were increased in the SCL group, indicating flattening of the corneal curvature. Differences between groups at central and superior corneal locations were not found to be statistically significant (see table 3).

## Corneal curvature at first visit

	SCL group (n=45)	NCL group (n=45)	Sig
<b>SimK Flat (D)</b>	42.98 ± 1.25	42.56 ± 1.31	0.12
<b>SimK Steep (D)</b>	43.67 ± 1.22	43.44 ± 1.42	0.42
<b>Sagittal radius superior (mm)</b>	7.78±0.26	7.80±0.27	0.63
<b>Sagittal radius central (mm)</b>	7.81±0.23	7.86±0.25	0.27
<b>Sagittal radius inferior (mm)</b>	7.72±0.21	7.79±0.29	0.20
<b>Tangential radius superior (mm)</b>	7.83±0.32	7.81±0.34	0.81
<b>Tangential radius central (mm)</b>	7.84±0.26	7.93±0.26	0.12
<b>Tangential radius inferior (mm)</b>	7.77±0.30	7.90±0.30	0.04*

*Table 3: Mean± SD and two-way ANOVA statistics for corneal curvature measured at first visit prior to SCL cessation for SCL and NCL groups. \*Statistically significant differences ( $p < 0.05$ ).*

The influence of SCL material and years of SCL wear on corneal curvature were explored. Results showed there was a mean decrease in Sagittal radii (indicating inferior steepening), relative to central and superior locations, present in the hydrogel group. The SiH group showed increased central radii (indicating flattening), relative to superior and inferior locations for both Sagittal and Tangential radii. All radius of curvature values were increased, indicating flattening with increasing years of SCL wear. However, the type of SCL material and years of SCL wear were found to have no statistically significant effect on corneal curvature (SimK, Sagittal or Tangential radius of curvature) ( $p > 0.05$ ).

The influence of SCL wearing modality was explored at the first visit. Results of two-way ANOVA testing revealed a statistically significant difference in Tangential inferior curvature on the anterior corneal surface for SCL modality of wear (NCL, daily wear (DW) and extended wear (EW)). Post-hoc Scheffe testing revealed this difference to be significant

between the NCL and EW SCL wearers only (NCL:  $6.34 \pm 0.32\text{mm}$ , DW:  $6.29 \pm 0.30\text{mm}$ , EW:  $6.02 \pm 0.42\text{mm}$ ;  $F(1:88): 4.55$ ,  $\text{Sig}=0.013$ ).

Comparison of corneal topographical indices data showed the vertical asymmetry and keratoconus index to be higher in the SCL group, this difference was statistically significant for the keratoconus index. The mean  $\pm$  SD keratoconus index value found ( $1.02 \pm 0.17$ ) was lower than the accepted abnormal or pathological values ( $>1.07$ ) as published by the manufacturer [29]. This index may have been elevated due to changes in corneal shape induced by SCL wear, such as the inferior steepening, which was evident on Tangential radii measured. The influence of SCL material and years of SCL wear on topographical indices was explored. The keratoconus index was higher in the hydrogel group compared with the SiH and NCL groups. There was a tendency for the corneal indices to increase with increasing years of SCL wear. However, the results of both the two-way ANOVA and Mann Whitney U testing showed there was no statistically significant effect of SCL material, or years of SCL wear or the interaction between SCL material and years of wear on topographical indices tested.

### **Corneal curvature at second visit**

Following two weeks cessation of SCL wear, the average difference in curvature for the SCL group showed a mean steepening of SimK values, while SimK values measured in the NCL group showed a mean flattening compared to values found at the first visit. However, there were no statistically significant differences in SimK values between the study groups (Table 4). Sagittal radii were found to remain stable in both SCL and NCL between first and second visits. The results of the two-way ANOVA and Kruskal Wallis testing for the differences in Tangential radii between first and second visits showed a statistically significant difference for the inferior Tangential radius of curvature value ( $p=0.02$ ,  $Z=0.00$ ), (see table 4). This

measurement showed a mean flattening of inferior Tangential radii in the SCL group ( $-0.08 \pm 0.18\text{mm}$ ) following cessation of SCL wear. This could indicate a resolution of inferior steepening and corneal warpage in the SCL group following cessation of lens wear as the cornea returned to a prolate shape. A comparison of the SCL and NCL group following lens cessation indicated no significant difference in inferior Tangential radii (SCL:  $7.82 \pm 0.26\text{mm}$ , NCL:  $7.89 \pm 0.32\text{mm}$ , sig: 0.30).

**Difference between corneal curvature measurements at first and second visit.**

	<b>SCL group Mean <math>\pm</math> SD n=38</b>	<b>NCL group Mean <math>\pm</math> SD n=37</b>	<b>Sig P value Two-way ANOVA</b>	<b>Sig Z value Kruskal- Wallis</b>
<b>Flattest K (D)</b>	-0.09 $\pm$ 0.32	0.06 $\pm$ 0.52	0.62	-
<b>Steepest K(D)</b>	-0.03 $\pm$ 0.25	0.10 $\pm$ 0.59	0.56	-
<b>Superior Sagittal radius (mm)</b>	-0.00 $\pm$ 0.01	-0.01 $\pm$ 0.01	0.83	0.14
<b>Central Sagittal radius (mm)</b>	0.00 $\pm$ 0.01	-0.02 $\pm$ 0.12	0.12	0.17
<b>Inferior Sagittal radius (mm)</b>	0.01 $\pm$ 0.08	-0.01 $\pm$ 0.09	0.21	0.45
<b>Superior Tangential radius (mm)</b>	-0.05 $\pm$ 0.17	-0.05 $\pm$ 0.17	0.98	0.59
<b>Central Tangential radius (mm)</b>	0.00 $\pm$ 0.89	-0.02 $\pm$ 0.12	0.42	0.81
<b>Inferior Tangential radius (mm)</b>	-0.08 $\pm$ 0.18	0.01 $\pm$ 0.08	0.02*	0.00*

*Table 4: Mean  $\pm$  SD and statistical analysis of the differences in corneal curvature values taken at first and second visits. A negative value indicates steeper SimK(D) following lens cessation, while a positive value indicates steeper Sagittal and Tangential radius of curvature (mm) following lens cessation. \*Statistically significant differences between the groups ( $p < 0.05$ ).*

The hydrogel group showed relative corneal stability, while the SiH group showed a steepening of SimK values following cessation of lens wear. There was increased steepness in corneal curvature following lens cessation with increasing years of SCL wear. However, results showed no statistically significant differences between the groups (see Table 5).

**Influence of SCL material and years of SCL wear on the difference in corneal curvature values measured at first and second visit.**

<b>Mean± SD</b>	<b>NCL n=37</b>	<b>Hydrogel n=32</b>	<b>SiH n=6</b>	<b>Sig</b>	<b>Short term n=9</b>	<b>Medium term n=19</b>	<b>Long term n=7</b>	<b>Sig</b>
<b>SimK Flat (D)</b>	0.06 ± 0.53	-0.02 ± 0.26	-0.18 ± 0.31	0.37	0.02 ± 0.34	-0.06 ± 0.20	-0.10 ± 0.37	0.54
<b>SimK Steep (D)</b>	0.10 ± 0.60	0.01 ± 0.19	-0.03 ± 0.12	0.86	0.04 ± 0.30	0.01 ± 0.13	-0.04 ± 0.08	0.56
<b>Superior Sagittal radius (mm)</b>	-0.01 ± 0.10	-0.01 ± 0.05	-0.05 ± 0.08	0.38	0.00 ± 0.08	-0.02 ± 0.05	-0.04 ± 0.05	0.67
<b>Central Sagittal radius (mm)</b>	-0.02 ± 0.12	0.02 ± 0.05	0.02 ± 0.05	0.65	-0.03 ± 0.12	0.02 ± 0.06	0.05 ± 0.05	0.46
<b>Inferior Sagittal radius (mm)</b>	-0.01 ± 0.09	0.01 ± 0.09	0.02 ± 0.06	0.78	-0.01 ± 0.07	0.01 ± 0.09	0.04 ± 0.09	0.67
<b>Superior Tangenti al radius (mm)</b>	-0.05 ± 0.17	-0.05 ± 0.18	-0.05 ± 0.13	0.92	-0.1 ± 0.09	-0.05 ± 0.22	0.01 ± 0.08	0.63
<b>Central Tangenti al radius (mm)</b>	-0.02 ± 0.12	-0.01 ± 0.08	-0.02 ± 0.06	0.80	-0.07 ± 0.07	0.00 ± 0.06	0.04 ± 0.09	0.15
<b>Inferior Tangenti al radius (mm)</b>	0.01 ± 0.08	-0.05 ± 0.14	-0.21 ± 0.3	0.02*	-0.04 ± 0.2	-0.11 ± 0.19	-0.06 ± 0.11	0.36

*Table 5: Mean ± SD of differences in corneal curvature between first and second visits for SCL material and years of SCL wear. A negative value indicates steeper SimK (D) following lens cessation, while a positive value indicates steeper Sagittal and Tangential radius of curvature (mm) following lens cessation. \*Statistically significant differences between the groups ( $p < 0.05$ ).*

While the hydrogel group showed stability of anterior Sagittal radii of curvature, the SiH group showed flattening of superior Sagittal radii and steepening of central and inferior Sagittal radii following cessation of SCL wear, (see Table 5). These results were not statistically significant. Tangential radii measured superiorly and inferiorly were flatter in the SiH group, with the largest change occurring at the inferior location. The results of the two-way ANOVA exploring the effect of SCL material for Tangential radii, showed the differences between the groups to be statistically significant at this inferior location,  $(-0.21 \pm 0.30\text{mm}, F(2,65)=4.02, p=0.02)$ . There was a tendency for differences in radii to be steeper at the second visit with increasing years of SCL wear, however, this was not statistically significant.

The influence of SCL wearing modality was also explored following two weeks cessation of SCL wear, at the second visit there were no statistically significant differences in corneal curvature for SCL modality groups (NCL, DW or EW).

Corneal topographic indices were also tested at the second visit. Statistical analysis found there were no statistically significant differences in corneal topographical indices between study groups at this visit (SCL vs. NCL). This evidence again supports the assumption that inferior corneal steepening seen on Tangential inferior curvature prior to cessation of SCL wear had resolved, indicating a resolution in corneal warpage in the SCL group, following two weeks of SCL wear cessation.



## Discussion

In this study, corneal curvature was examined using the Pentacam (Oculus, Germany). This instrument has been found to be highly reliable and show excellent repeatability in previous studies [28, 30-33].

It is well established that anterior corneal keratometry and curvature values steepen with SCL wear [7-10]. Our results found this steepening was only statistically significant for the Tangential radii measured at the inferior location on the cornea. This finding is in agreement with authors who reported increased irregularity of corneal curvature and corneal warpage or pseudo-keratoconic topography with SCL wear [6, 11, 12]. Contact lens-induced corneal warpage is particularly evident with rigid CL wear but up to 27.5% of reported cases have been associated with SCL wear [3, 34-37].

Corneal topography is the most sensitive tool used in the analysis of CL- induced corneal warpage [5]. It is vital to be able to differentiate true forme fruste keratoconus from CL- induced corneal warpage. However, our study corroborates reports that demonstrate the use of different corneal curvature descriptors is important[38]. Tangential curvature was the only descriptor able to identify subtle differences in curvature caused by SCL wear. Sagittal and Tangential topography are similar at the centre of the cornea, but as the cornea is an aspheric surface, they differ in the periphery with the Tangential curvature becoming greater than the Sagittal[39]. Our findings indicate that corneal irregularity caused by myopic SCL wear is evident at the mid-peripheral cornea.

The Sagittal radius assumes the centre of curvature for a specific surface point is located on the optical axis, which is true only if the surface is spherical. As most corneas are spherical at the apex, this assumption is acceptable for keratometry. However, with normal prolate shape,

this assumption induces errors when measuring the corneal periphery where the centres of curvature depart from the optical axis [40].

In contrast, Tangential radius of curvature is the measure of the curvature at each point with respect to its neighbouring points. Tangential curvature measurements do not assume normal incident rays and are more accurate towards the periphery. It is more sensitive than Sagittal curvature to subtle deviations from the normal corneal shape such as keratoconus [41-43].

Therefore, Tangential radius of curvature is more practical for detecting local irregularities in corneal shape such as those induced by refractive surgery, CL wear or ectasia and in the examination of the peripheral cornea[38, 41]. Our results evidence this fact as no differences between were detected using Sagittal radii, however Tangential radii demonstrated steepening of the inferior cornea.

The effect of Hydrogel and SiH lens materials and previous years of SCL wear were examined in the SCL group and results were compared to the NCL control group. Our results indicate that there was more corneal warpage (superior flattening and inferior steepening of both Sagittal and Tangential radii) present in the hydrogel SCL group compared to the NCL group. It has been proposed that these changes may be explained through hypoxia-associated corneal thinning in low-DK/t hydrogel wearers[6, 11, 12]. However, no statistically significant differences were found between the groups in the present study. The lack of statistical significance may be due to reduced previous years of SCL wear with low DK/t hydrogel lenses. When extended wear modalities are required, most practitioners now fit SiH lenses. Therefore, there may not be sufficient hypoxia present in our hydrogel group to result in significant corneal warpage.

Our results found that SiH lens materials, worn over EW modalities, resulted in the most prominent alterations to corneal curvature. SiH lens wear can induce mechanical related

changes in the cornea[44, 45], these can result in flattening of keratometry values [6, 14-18]. The flattening may be due to a pressure-related change in corneal tissue in the stiffer (higher modulus) SiH materials [44, 45]. In agreement with this, our results showed the central radius of curvature was flatter than the inferior and superior cornea in the SiH group. However, overall curvature values were steeper than both the hydrogel and the NCL groups. Again, the Tangential radius of curvature showed inferior corneal steepening to be present in the SiH group and most specifically within the EW modality. As the sample size of the SiH wearers was small (n=6, n=3 DW, n=3 EW) one cannot definitively draw conclusions regarding the differences in the effects of hydrogel and SiH lens materials or the influence of EW modalities on corneal curvature stability following cessation of SCL wear. One would expect the stiffer modulus in generation 1 SiH lenses to result in increased corneal warpage when compared to the lower modulus found in generation 2 and 3 SiH lenses. Further research is required to clearly identify the extent of corneal warpage occurring due to different moduli present with the various generations of SiH materials, and also the effect of extended versus daily wear modalities within these same SiH materials.

The toric SCL wearers (n=2) in this study utilised dynamic stabilisation techniques in their SCLs. It would be worthwhile in future research to examine the influence of different thicknesses of SCL on the stability of corneal curvature, with the inclusion of prism ballast toric SCLs and SCLs to treat hyperopia. The thicker areas of these SCLs will result in reduced DK/t and so may increase the amount of corneal warpage seen inferiorly with the prism ballast or centrally with the hyperopic SCL wearers.

Following two weeks cessation of SCL wear, all corneal curvature measurements showed relative stability except for the Tangential radii measured at the inferior cornea. This measurement showed a significant flattening in the SCL group. This could indicate that there

was a resolution of inferior steepening and corneal warpage in the SCL group following cessation of CL wear as the cornea demonstrated a prolate shape.

At the time these patients attended for surgery, it was common practice to conclude measurements after two weeks if these demonstrated corneal stability. This opens the question ‘had measurements been repeated a third occasion, would these demonstrate further changes? While Tangential curvature was not measured again after this two week time period it was proposed that resolution of corneal warpage had occurred as there was no significant difference between the SLC and NCL group for either Tangential curvature or corneal topographic indices at the second visit.

Contact lens material had an influence on the resolution of corneal curvature changes. The hydrogel SCL group showed relative stability in SimK and Sagittal radius of curvature values following cessation of SCL wear. These results were comparable to the NCL control group, with no statistically significant differences between the groups tested.

Flattening of Tangential radii in the hydrogel group was greatest in superior and inferior locations and relatively small in the central location, indicating a return to prolate shape following cessation of SCL wear. While flattening was also present in the hydrogel group, the results were comparable to the NCL group.

In contrast to this, the use of SiH materials appeared to result in the most influential changes to Tangential radii. The largest flattening was seen in the SiH group at the inferior corneal location, this result was statistically significant ( $0.21 \pm 0.30\text{mm}$ ,  $F(2, 65) = 4.02$ ,  $p = 0.02$ ,  $\eta^2 = 0.11$ ). As the resolution of inferior steepening was significant only for the Tangential mid-peripheral radius of curvature, this finding emphasises the importance of using Tangential radius of curvature for peripheral corneal curvature analysis in SCL and CRS patients.

The standard values given for stability of curvature measurements following cessation of CL wear is less than 0.50D or 0.1mm change since the previous visit [21]. Using these criteria, only the inferior Tangential radii measured in the SiH SCL group showed instability of measurements following cessation of SCL wear over a two-week period.

Time to resolution of corneal warpage following cessation of CL wear has been reported to vary according to lens material and previous years of SCL wear [20]. Our results showed SCL induced corneal curvature changes appeared to have resolved following two weeks cessation of CL wear. Methodology, including the degree of initial corneal warpage present and manner in which corneal topography is analysed, can influence the statistical analysis and results of these studies. Wang et al. assessed corneal warpage in long term CL wearers (mean time 21.2 years, range 10 to 30 years) and found corneal warpage to be present in 12% (n=20 eyes) of CRS candidates [21]. The mean recovery time for corneal warpage in these patients was  $7.8 \pm 6.7$  weeks; the large standard deviation may represent the inclusion of a large variety of CL materials and modalities of wear. Longest recovery times ( $11.6 \pm 8.5$  weeks) were found for the SCL extended wear group (n=6). This was longer even than rigid gas permeable (RGP) lens wearers (n=8) ( $8.8 \pm 6.8$  weeks). However, it was not specified whether the SCL material for extended wear was hydrogel or SiH. Shortest recovery times were found for SCL daily wearers (n=2,  $2.5 \pm 2.1$  weeks). Wang et al. evaluated the stability in SimK values and explored the reversal of the normal prolate topographic pattern. It was not stated whether Sagittal or Tangential radial patterns were analysed.

Ng et al. [22] reported that extended hydrogel wearers take the longest time to achieve corneal stability following cessation of SCL wear, while SiH extended wearers followed by hydrogel daily wearers took the shortest time. The overall mean time for stability for the SCL group (n=15) was  $16.2 \pm 17.5$  days for keratometry and  $28.1 \pm 17.7$  days for Sagittal radii. The control group (n=5) showed little variability between the methods of stabilization

assessment. Ng et al. acknowledged that keratometry resolved in a shorter time period than Sagittal topography. Tangential radius of curvature was not examined in this study.

Hashemiet al. evaluated corneal curvature stability following the removal of SCLs and following this, on day 3, 7 and weekly thereafter. Criteria for stability were less than 0.50D or 0.1mm change in SimK between visits [21]. The reversal of normal prolate topography patterns was also analysed. Forty-two eyes (21 patients) were examined, 14 eyes (30%) fulfilled stability criteria after the first assessment. Seven eyes (15%) were grouped as unstable and required at least 1 week to achieve stability. Analysis into the predictability of stability time did not yield any firm associations between the risk of instability with refractive data, topography or duration of CL wear. The authors were unable to report on differences related to CL materials or comparisons with a NCL group. It was concluded that the majority of patients reached corneal topographical stability following a two-week SCL cessation period. However, it was noted that for some patients this may not be sufficient and a better approach would be to take repeated scans prior to CRS in order to document stability.

Discrepancies between these studies and our results might be related to the exclusion of extended wear hydrogel SCL wearers, confirmed cases of SCL warpage and as previously discussed the small number of SiH and EW SCL wearers in our study. If recognisable inferior steepening ( $>1.4D$ ) was present at the first visit, forme fruste keratoconus was suspected and these patients were advised they were not suitable candidates for CRS. Furthermore, in our study the only statistically significant differences found were in the analysis of mid-peripheral Tangential radii. This method of analysis was not employed by previous studies into time to resolution of corneal curvature changes.

Our study focused on the stability of corneal curvature measurements following cessation of SCL wear. When considering stability prior to CRS one must also consider manifest refraction and visual acuity data. The clinical protocol at the time of surgery for the patients in this study did not include a manifest refraction at first visit. As the current study is a retrospective analysis, it was not possible to assess if best-corrected spectacle VA or manifest refraction was stable between the two visits prior to surgery. This is an interesting point that should be considered in future studies. In this study, we followed the current FDA guidelines regarding two weeks cessation of SCL wear prior to CRS. As only two measurements were taken at first visit, prior to SCL cessation and at the second visit, following two weeks SCL cessation, we cannot provide an absolute period for each patient in relation to SCL cessation. Future studies are required to document the exact time required for VA, manifest refraction and corneal curvature stability to occur.

## **Conclusion**

Our results confirmed that caution should be exercised when assessing the suitability of patients for CRS procedures if they are SCL wearers. In some cases, suspicious topography may be missed if only keratometry or Sagittal radius of curvature are examined. Suspicious corneal inferior steepening may be more evident by analysis of Tangential radii. Two weeks appears to be sufficient for resolution of ‘pre-clinical’ SCL induced corneal curvature changes with modern SCL materials especially if worn on daily wear modalities. However, repeated measurements should be taken to ensure stability for all SCL wearing patients.

## References

1. FDA, U.S.F.D.A., *Medical devices. Products and medical procedures. Surgery and life support devices*, U.S.D.o.H.a.H. Services, Editor. 2011: Silver Springs, MD.
2. Hashemi, H., et al., *Corneal stability after discontinued soft contact lens wear*. British Contact Lens Association, 2008(31): p. 122-125.
3. Schornack, M., *Hydrogel contact lens-induced corneal warpage* Contact lens & Anterior Eye, 2003(26): p. 153-159.
4. Nourouzi, H., J. Rajavi, and M. Okhovaatpour, *Time to resolution of corneal edema after long-term contact lens wear*. American Journal of Ophthalmology, 2006. **142**(4): p. 671-673.
5. Hoyos, J. and M. Cigales (2002) *Topographical and pachymetric changes induced by contact-lenses*. Keratomileusis Study Group Journal, 1-8.
6. Alba-Bueno, F., et al., *Corneal shape changes induced by first and second generation silicone hydrogel contact lenses in daily wear*. Contact Lens & Anterior Eye, 2009. **32**(8): p. 88-92.
7. Yenziad, B., et al., *Effects of contact lenses on corneal thickness and corneal curvature during usage*. Eye & Contact lens, 2003. **29**: p. 223-229.
8. Jalbert, I., et al., *Changes in myopia with low-DK hydrogel and high-DK silicone hydrogel extended wear*. Optometry and Vision Science, 2004. **81**: p. 591-596.
9. Collins, M.J. and A.S. Bruce, *Soft contact lenses and corneal topography*. International Contact Lens Clinic, 2004. **20**(9-10): p. 187-190.
10. Liu, Z. and S. Pflugfelder, *The effects of long-term contact lens wear on corneal thickness, curvature, and surface regularity*. Ophthalmology, 2000. **107**(1): p. 105-111.
11. Arranz, I., et al., *Low water content hydrogel contact lenses (HCL) induce corneal irregularity*. Investigative Ophthalmology & Visual Science, 2003. **44**(370-404).
12. Cheng, X., et al., *Validation of a clinical Shack-Hartmann aberrometer*. Optometry and Vision Science, 2003. **80**(8): p. 587-595.
13. Guillon, M. and C. Maïssa, *Long-term effects of the daily wear of senofilcon A silicone hydrogel contact lenses on corneal and conjunctival tissues*. Optometry - Journal of the American Optometric Association, 2010. **81**(12): p. 680-687.
14. Bergenske, P., et al., *Long-term clinical results: 3 years of up to 30-night continuous wear of Iotrafilcon A silicone hydrogel and daily wear of low-DK / t hydrogel lenses*. Eye Contact Lens, 2007. **33**: p. 74-80.
15. Schorner, S. (2010) *Some facts about SiHy lenses*. Review of Optometry.
16. Gonzalez-Meijome, J., et al., *Changes in corneal structure with continuous wear of high-DK soft contact lenses: a pilot study*. Optometry and Vision Science, 2003. **80**: p. 440-446.
17. Liesegang, T., *Physiologic Changes of the Cornea with Contact Lens Wear* Contact Lens and Anterior Eye, 2002. **28**(1): p. 12-27.
18. Dumbleton, K., et al., *Objective and subjective responses in patients refitted to daily wear silicone hydrogel contact lenses*. Optometry and Vision Science, 2006. **83**(10): p. 758-768.
19. Tsai, P., et al., *Predicting time to refractive stability after discontinuation of rigid contact lens wear before refractive surgery*. Journal of Cataract and Refractive Surgery, 2004. **30**: p. 2290-2293.



20. Wang, X., et al., *Time to resolution of contact lens-induced corneal warpage prior to refractive surgery*. The Contact Lens Association of Ophthalmologists Journal, 2002. **28**(4): p. 169-171.
21. Ng, L., M. Lee, and A. Nguyen, *Preoperative assessment of corneal and refractive stability in soft contact lens wearing photorefractive candidates*. Optometry and Vision Science, 2007. **84**(5): p. 401-409.
22. World Medical Association, *Declaration of Helsinki- ethical principles for medical research involving human subjects*. 2008: Seoul. p. 1-6.
23. Katz, J., S. Zeger, and K. Liang, *Appropriate statistical methods to account for similarities in binary outcomes between fellow eyes*. Investigative Ophthalmology & Visual Science, 1994. **35**(5): p. 2461-2465.
24. Ederer, F., *Shall We Count Numbers of Eyes or Numbers of Subjects?* Archive of Ophthalmology, 1973. **89**: p. 1-2.
25. Glynn, R. and B. Rosner, *Accounting for the correlation between fellow eyes in regression analysis* Archive of Ophthalmology, 1992. **110**: p. 381-387.
26. Erdfelder, E., F. Faul, and A. Buchner, *GPOWER: A general power analysis program*. Behaviour Research Methods, Instruments & Computers, 1996. **28**(1): p. 1-11.
27. Mendes, M. and A. Pala, *Type I Error Rate and Power of Three Normality Tests*. Pakistan Journal of Information and Technology, 2003. **2**(2): p. 135-139.
28. Read, S. and M. Collins, *Diurnal variation of corneal shape and thickness*. Optometry and Vision Science, 2009. **86**(3): p. 170-180.
29. Oculus, *Pentacam instruction manual*, Oculus, Editor. 2007: Wetzlar. p. 38.
30. Hashemi, H. and S. Mehravaran, *Central corneal thickness measurement with Pentacam, Orbscan II, and ultrasound devices before and after laser refractive surgery for myopia*. Journal of Cataract & Refractive Surgery, 2007. **33**(10): p. 1701-1707.
31. Kawamorita, T., N. Nakayama, and H. Uozato, *Repeatability and reproducibility of corneal curvature measurements using the Pentacam and Keratron systems*. Journal of Refractive Surgery, 2009a. **25**(6): p. 539-544.
32. Chen, D. and A. Lam, *Reliability and repeatability of the pentacam on corneal curvatures*. Clinical and Experimental Optometry, 2009. **92**(2): p. 110-118.
33. O'Donnell, C. and C. Maldonado-Codina, *Agreement and repeatability of central thickness measurment in normal corneas using Ultrasound pachymetry and the Oculus Pentacam*. Cornea, 2005. **24**(8): p. 920-924.
34. Michaud, L. *Late development of ectasia or corneal warpage secondary to continuous wear of a SiH lens* In the practice. Ciba Vision Silicone Hydrogels [cited 2009 04/06/2009].
35. Klyce, S.D., *Corneal topography and contact lenses*, in *Commission on Behavioral and Social Sciences and Education (CBASSE)*. 1991.
36. Ryan, R. and P. Jacob, *Corneal warpage: not just for rigid lens wearers*. Contact Lens Spectrum, 1996(September 1996): p. 1-2.
37. Tseng, S., J. Hsiao, and D. Chang, *Mistaken diagnosis of keratoconus because of corneal warpage induced by hydrogel lens wear*. Cornea, 2007. **26**: p. 1153-1155.
38. El Hage, S. and N. Leach, *Tangential or sagittal dioptric plots: is there a difference?* ICLC, 1999. **26**: p. 39-45.
39. Corbett, M., E. Rosen, and D. O'Brart, *Assessment of corneal shape*, in *Corneal topography: principles and applications*. 1999, BMJ publishing group: London.
40. Klyce, S., *Corneal topography and the new wave*. Cornea, 2000. **19**(5): p. 723-729.

41. Pascucci, S., *Comprehensive analysis, clinical benefits. Surgical screening using the pentacam.* . Cataract and Refractive Surgery Today, 2007. **Supplement to July 2007**: p. 3-5.
42. Klein, S. and R. Mandell, *Axial and instantaneous power conversions in corneal topography.* Investigative Ophthalmology and Visual Science, 1995a. **36**(10): p. 2155-2159.
43. Klein, S. and R. Mandell, *Shape and refractive powers in corneal topography.* Investigative Ophthalmology and Visual Science, 1995b. **36**(10): p. 2096-2109.
44. Holden, B.A., et al., *Superior Epithelial Arcuate Lesions with Soft Contact Lens Wear.* Optometry & Vision Science, 2001. **78**(1): p. 9-12.
45. Sweeney, D., *Clinical signs of hypoxia with high-Dk soft lens extended wear: Is the cornea convinced?* Eye & Contact Lens, 2003. **29**(1): p. S22-S25.